## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

)	MDL NO. 1456
IN RE PHARMACEUTICAL INDUSTRY )	
AVERAGE WHOLESALE PRICE )	CIVIL ACTION: 01-CV-12257-PBS
LITIGATION )	
)	JUDGE PATTI B. SARIS
)	
THIS DOCUMENT RELATES TO:	
)	
State of Montana v. Abbott Labs., Inc., et al.,)	
D. Mont. Cause No. CV-02-09-H-DWM )	
)	

## ANSWER OF B. BRAUN OF AMERICA INC. TO STATE OF MONTANA'S SECOND AMENDED COMPLAINT

#### I. INTRODUCTION

1. Defendant B. Braun of America Inc. (hereinafter "BBA") admits that the above-captioned lawsuit has been filed against it. All other allegations contained in Paragraph 1 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 1 of the Second Amended Complaint as they relate to defendants other than BBA.

As stated in its Motion to Dismiss, BBA is not a proper party to this litigation. This Court lacks jurisdiction and venue over BBA. Moreover, BBA neither manufactures nor sells any of the pharmaceuticals listed either in Paragraph 347 of the Second Amended Complaint or in Appendix A attached thereto. BBA's Answer is in no way intended to be a waiver of its position that it is not properly before this Court.

- 2. The allegations contained in the first sentence of Paragraph 2 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 2 of the Second Amended Complaint.
- 3. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 3 of the Second Amended Complaint.
- The allegations contained in the first sentence of Paragraph 4 of the Second 4. Amended Complaint are denied. The allegations contained in the second sentence of Paragraph 4 are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the allegations contained in the second sentence of Paragraph 4 as they relate to defendants other than BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the third and fourth sentences of Paragraph 4 of the Second Amended Complaint. allegations contained in the fifth sentence of Paragraph 4 are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the fifth sentence of Paragraph 4 of the Second Amended Complaint as they relate to defendants other than BBA. BBA admits that the Attorney General of Montana has brought the instant action. All remaining allegations contained in the sixth sentence of Paragraph 4 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in the sixth sentence of Paragraph 4 as they relate to defendants other than BBA.

#### A. Defendant's Unlawful Schemes

- 5. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 5 of the Second Amended Complaint.
- 6.-10. The allegations contained in Paragraphs 6-10 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 6-10 of the Second Amended Complaint as they relate to defendants other than BBA.
- 11.-12. The plaintiff's claims relating to "Best Price" have been dismissed by the Court's Memorandum and Order dated June 10, 2004. Nonetheless, the allegations contained in Paragraphs 11-12 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 11-12 as they relate to defendants other than BBA.

#### B. The Damages Caused by Defendants' Illegal Conduct

13. The allegations contained in Paragraph 13 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 13 of the Second Amended Complaint as they relate to defendants other than BBA.

#### 1. Damages to the State of Montana

14. The allegations contained in Paragraph 14 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 14 of the Second Amended Complaint as they relate to defendants other than BBA.

- 15. Claims relating to "Best Price" have been dismissed by the Court's Memorandum and Order dated June 10, 2004. Nonetheless, the allegations contained in Paragraph 15 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 15 of the Second Amended Complaint as they relate to defendants other than BBA.
- 16.-17. The allegations contained in Paragraphs 16-17 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 16-17 of the Second Amended Complaint as they relate to defendants other than BBA.
- 18. BBA admits that the State seeks to recover actual damages in this case. The remaining allegations contained in Paragraph 18 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 18 of the Second Amended Complaint as they relate to defendants other than BBA.

#### 1. Damages to Patients

- 19.-20. The allegations contained in Paragraphs 19-20 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 19-20 of the Second Amended Complaint as they relate to defendants other than BBA.
- 21. BBA admits that Montana seeks damages on behalf of its citizens. The remaining allegations contained in Paragraph 21 of the Second Amended Complaint are denied.

#### C. The Objectives of This Action

- 22. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 22 of the Second Amended Complaint.
- 23. The plaintiff's claims relating to "Best Price" have been dismissed by the Court's Memorandum and Order dated June 10, 2004. Nonetheless, the allegations contained in Paragraph 23 are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 23 of the Second Amended Complaint as they relate to defendants other than BBA.

#### II. PARTIES

#### A. Plaintiff

- 24. BBA admits that the State of Montana has asserted claims as specified in the Second Amended Complaint. The plaintiff's claims relating to "Best Price" have been dismissed by the Court's Memorandum and Order dated June 10, 2004. The remaining allegations contained in Paragraph 24 of the Second Amended Complaint are denied.
- 25. BBA admits that the Montana Medicaid Program exists. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 25 of the Second Amended Complaint.
- 26.-28. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 26-28 of the Second Amended Complaint.

#### B. Defendants

29.-30. The allegations contained in Paragraphs 29-30 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to

form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 29-30 of the Second Amended Complaint as they relate to defendants other than BBA.

#### 1. Abbott

31.-33. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 31-33 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 2. Amgen

33.-34. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 33-34 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 3. AstraZeneca

35.-39. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 35-39 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 4. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

40.-45. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 40-45 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 5. Baxter

46.-49. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 46-49 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 6. Bayer

50.-52. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 50-52 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 7. The Boehringer Group (Boehringer, Ben Venue, Bedford)

53.-57. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 53-57 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 8. Braun

- 58. The allegations contained in the first sentence of Paragraph 58 of the Second Amended Complaint are admitted. BBA denies the remaining allegations contained in Paragraph 58 of the Second Amended Complaint.
- 59. BBA admits that McGaw, Inc. was a Delaware corporation with its principal place of business in Irvine, California, and that McGaw, Inc. was in the business of manufacturing and distributing intravenous solutions. BBA admits that McGaw, Inc. was acquired in 1997 and merged into a corporate entity separate from BBA. BBA admits that B. Braun Medical Inc. designs, manufactures, and markets medical devices, certain intravenous solutions, and some prescription pharmaceuticals. BBA is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegation contained in the fourth sentence of Paragraph 59 of the Second Amended Complaint that prescription pharmaceuticals manufactured by McGaw, Inc. were distributed by Medicare Plan B providers nationwide. BBA denies the allegation contained in the fifth sentence of Paragraph 59 of the Second Amended Complaint that BBA, B. Braun Medical Inc., and McGaw, Inc. may be treated or referred to as a

collective entity. All remaining allegations contained in Paragraph 59 of the Second Amended Complaint are denied as to BBA.

60. The allegations contained in Paragraph 60 of the Second Amended Complaint are denied as to BBA.

#### 9. The BMS Group (Bristol-Myers, Oncology Therapeutics Network, Apothecon)

61.-66. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 61-66 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 10. Dey

67.-69. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 67-69 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 11. The Fujisawa Group (Fujisawa Healthcare, Fujisawa USA)

70.-73. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 70-73 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 12. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

74.-79. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 74-79 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 13. Immunex

80.-82. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 80-82 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 14. The Johnson & Johnson Group (J&J, Centocor, Janssen, McNeil, Ortho)

83.-88. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 83-88 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 15. Novartis

89.-90. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 89-90 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 16. Pfizer

91.-92. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 91-92 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 17. The Pharmacia Group (Pharmacia and Pharmacia & Upjohn)

93.-96. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 93-96 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 18. The Schering-Plough Group (Schering Plough & Warrick)

97.-100. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 97-100 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 19. The Sicor Group (Sicor and Gensia)

101.-106. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 101-106 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 20. TAP

107.-109. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 107-109 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 21. Watson.

110.-111. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 110-111 of the Second Amended Complaint. These allegations are directed at another defendant.

## III. PRESCRIPTION DRUG SPENDING IN THE UNITED STATES HAS INCREASED DRAMATICALLY, DISPROPORTIONATELY IMPACTING THE POOR AND ELDERLY

112. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 112 of the Second Amended Complaint.

#### A. Increases in Prescription Drug Costs Generally

113.-115. Paragraphs 113-115 of the Second Amended Complaint contain allegations based on information allegedly contained in The Kaiser Family Foundation, Prescription Drug Trends: A Chartbook (July 2000) and The Kaiser Family Foundation, Prescription Drug Trends: A Chartbook Update (November 2001). BBA admits that such publications exist and that those publications speak for themselves. BBA denies the plaintiff's interpretation and characterization of the contents of those publications. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 113-115 of the Second Amended Complaint.

#### B. Impacts on Medicaid Programs

- 116.-117. Paragraphs 116-117 of the Second Amended Complaint contain allegations based on information allegedly contained in The Kaiser Family Foundation, Prescription Drug Trends: A Chartbook Update (November 2001). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 116-117 of the Second Amended Complaint.
- 118. Paragraph 118 of the Second Amended Complaint contains allegations based on information allegedly contained in The Kaiser Family Foundation, Medicare and Prescription Drugs Fact Sheet (April 2003). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. In all other respects, BBA is without

sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 118 of the Second Amended Complaint.

#### C. Impacts on the Medicare Program and the Elderly

- 119. Paragraph 119 of the Second Amended Complaint contains allegations based on information allegedly contained in The Kaiser Family Foundation, Prescription Drug Trends: A Chartbook Update (November 2001). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. Exhibit No. 10, referenced on the page of the publication cited by the plaintiff in Paragraph 119, states that these figures are *not* related to spending in the Medicare Program, as alleged by the plaintiff in Paragraph 119, and this allegation is, therefore, denied. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 119 of the Second Amended Complaint.
- 120. Paragraph 120 of the Second Amended Complaint contains allegations based on information allegedly contained in The Kaiser Family Foundation, Prescription Drug Trends: A Chartbook (July 2000) and The Kaiser Family Foundation, Prescription Drug Trends: A Chartbook Update (November 2001). BBA admits that such publications exist and that those publications speak for themselves. BBA denies the plaintiff's interpretation and characterization of the contents of those publications. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 120 of the Second Amended Complaint.
- 121. Paragraph 121 of the Second Amended Complaint contains allegations based on information allegedly contained in The Kaiser Family Foundation, Prescription Drug

TRENDS: A CHARTBOOK (July 2000). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 121 of the Second Amended Complaint.

- 122. The plaintiff offers no source or reference for the figures alleged in Paragraph 122 of the Second Amended Complaint. As a result, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 122 of the Second Amended Complaint.
- 123. The allegations contained in Paragraph 123 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the allegations contained in Paragraph 123 of the Second Amended Complaint as they relate to defendants other than BBA.

#### IV. THE PRESCRIPTION DRUG MARKET

124. The allegations relating to "frauds" and "schemes" contained in Paragraph 124 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 124 of the Second Amended Complaint.

#### A. Drug Classifications (Brand Name and Generic)

125. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 125 of the Second Amended Complaint.

- 126.-127. The allegations contained in Paragraphs 126-127 of the Second Amended Complaint are denied.
- 128. The allegations contained in the first sentence of Paragraph 128 of the Second Amended Complaint are denied. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 128 of the Second Amended Complaint.

#### B. The Distribution Channel

#### 1. Wholesalers

- 129. The allegations contained in Paragraph 129 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 129 of the Second Amended Complaint as they relate to defendants other than BBA.
- 130. Paragraph 130 of the Second Amended Complaint contains allegations based on information allegedly contained in The KAISER FAMILY FOUNDATION, PRESCRIPTION DRUG TRENDS: A CHARTBOOK (July 2000). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. The information cited by the plaintiff in the first sentence of Paragraph 130 is drawn from a chart contained on page 73 of the publication, not page 20, as indicated in Paragraph 130. By its own terms, the chart referenced on page 73 of the publication does not include BBA. Therefore, the allegations contained in the first sentence of Paragraph 130 of the Second Amended Complaint are denied as to BBA. The plaintiff does not identify the source of information used for the allegations contained in the second sentence of Paragraph 130 of the Second Amended Complaint. Therefore, BBA is without sufficient knowledge or

information so as to form a belief as to the truth or falsity of the specific allegations contained in the second sentence of Paragraph 130 of the Second Amended Complaint. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 130 of the Second Amended Complaint.

- 131. The allegations contained in Paragraph 131 of the Second Amended Complaint are denied as to BBA.
- 132. The allegations contained in the second sentence of Paragraph 132 of the Second Amended Complaint are denied. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 132 of the Second Amended Complaint.

#### 2. Retail pharmacies

- 133. Paragraph 133 of the Second Amended Complaint contains allegations based on information allegedly contained in The Kaiser Family Foundation, Prescription Drug Trends: A Chartbook (July 2000). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. By its own terms, the chart referenced on page 73 of the publication does not include BBA. Therefore, the allegations contained in Paragraph 133 of the Second Amended Complaint are denied as to BBA. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 133 of the Second Amended Complaint.
- 134. The allegations contained in Paragraph 134 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief

as to the truth or falsity of the specific allegations contained in Paragraph 134 of the Second Amended Complaint as they relate to defendants other than BBA.

- 135. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the allegations contained in the first sentence of Paragraph 135 of the Second Amended Complaint. The allegations contained in the second sentence of Paragraph 135 are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the second sentence of Paragraph 135 of the Second Amended Complaint as they relate to defendants other than BBA.
- 136-138. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 136-138 of the Second Amended Complaint.

#### 3. Physicians and others

- 139. Paragraph 139 of the Second Amended Complaint contains allegations based on information allegedly contained in The Kaiser Family Foundation, Prescription Drug Trends: A Chartbook (July 2000). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. By its own terms, the chart referenced on page 73 of the publication does not include BBA. Therefore, the allegations contained in Paragraph 139 of the Second Amended Complaint are denied as to BBA. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 139 of the Second Amended Complaint.
- 140. The allegations contained in Paragraph 140 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief

as to the truth or falsity of the specific allegations contained in Paragraph 140 of the Second Amended Complaint as they relate to defendants other than BBA.

141. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 141 of the Second Amended Complaint.

## V. GOVERNMENT REIMBURSEMENT SYSTEMS FOR PRESCRIPTION DRUGS

#### A. The Medicare Insurance Program

- 142.-143. The allegations contained in Paragraphs 142-143 of the Second Amended Complaint are admitted as to BBA.
- 144. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 144 of the Second Amended Complaint.
- 145. The first sentence of Paragraph 145 of the Second Amended Complaint contains allegations based on information allegedly contained in a publication entitled CCH, 2003 MEDICARE EXPLAINED. BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 145 of the Second Amended Complaint.
- 146. BBA admits that, pursuant to 56 FR 59502, 59621, effective January 1, 1992, 42 C.F.R. § 405.517(b) stated, in part, that "[p]ayment for a drug described in paragraph (a) of this section is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug." BBA further admits that, pursuant to 56 FR 59502, 59621, effective January

1, 1992, 42 C.F.R. § 405.517(c) stated that, "[f]or multiple-source drugs, payment is based on the lower of the estimated acquisition cost described in paragraph (b) of this section or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug." BBA admits that 56 FR 59502, 59621 was published in the Federal Register on November 25, 1991. The remaining allegations contained in Paragraph 146 of the Second Amended Complaint are denied.

147. BBA admits that, pursuant to 56 FR 59502, 59621, effective January 1, 1992, 42 C.F.R. § 405.517(b) stated, in part, that "[t]he estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, the carrier may consider factors such as inventory, waste, and spoilage." The remaining allegations contained in the first sentence of Paragraph 147 of the Second Amended Complaint are denied. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the second sentence of Paragraph 147 of the Second Amended Complaint.

148. BBA admits that, pursuant to 63 FR 58814, 58905, 42 C.F.R. § 405.517 was amended, effective January 1, 1999. BBA admits that, as amended, 42 C.F.R. § 405.517(b) states, in part, that "[p]ayment for a drug or biological . . . is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological." BBA further admits that, as amended, 42 C.F.R. § 405.517(c) states that "[f]or multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand

name forms of the drug or biological." All remaining allegations contained in Paragraph 148 of the Second Amended Complaint are denied.

- Amended Complaint are denied. BBA admits that Program Memorandum AB-99-63, dated September 1, 1999, reissued Program Memorandum AB-98-76, dated December 1, 1998. BBA admits that Program Memorandum AB-98-76 states, in part, that "[d]rugs and biologicals not paid on a cost or prospective payment basis are paid based on the lower of the billed charge or 95 percent of the AWP as reflected in sources such as the *Red Book*, *Blue Book*, or *Medispan*." All remaining allegations contained in Paragraph 149 of the Second Amended Complaint are denied.
- 150. BBA admits that Program Memorandum AB-99-63, dated September 1, 1999, reissued Program Memorandum AB-98-76, dated December 1, 1998. BBA admits that Program Memorandum AB-98-76 states, in part, that "[f]or a single-source drug or biological, the AWP equals the AWP of the single product." BBA admits that Program Memorandum AB-98-76 also states, in part, that "[f]or a multi-source drug or biological, the AWP is equal to the lesser of the median AWP of all of the generic forms of the drug or biological or the lowest brand name product AWP." All remaining allegations contained in Paragraph 150 of the Second Amended Complaint are denied.
- 151. BBA admits that there are no federal regulations defining "average wholesale price" or establishing the manner in which AWPs must be calculated. BBA admits that it does not report AWPs for any products to the federal government. The remaining allegations contained in Paragraph 151 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the

remaining allegations contained in Paragraph 151 of the Second Amended Complaint as they relate to defendants other than BBA.

- 152. BBA admits that Medicare may, in some instances, reimburse medical providers for administering a covered drug. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of Medicare's specific relationships with beneficiaries and providers. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 152 of the Second Amended Complaint.
- 153. The allegations contained in Paragraph 153 of the Second Amended Complaint are admitted.

#### B. The Medicaid Insurance Program

154. Paragraph 154 of the Second Amended Complaint contains allegations based on information allegedly contained in BRIAN K. BRUEN, MEDICAID AND PRESCRIPTION DRUGS: AN OVERVIEW (October 2000). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 154 of the Second Amended Complaint.

#### 1. Eligibility

155.-156. Paragraphs 155-156 of the Second Amended Complaint contain allegations based on information allegedly contained in BRIAN K. BRUEN, MEDICAID AND PRESCRIPTION DRUGS: AN OVERVIEW (October 2000). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. In all other respects, BBA is without

sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 155-156 of the Second Amended Complaint.

- 157. The first sentence of Paragraph 157 of the Second Amended Complaint contains allegations based on information allegedly contained in The Kaiser Commission on Medicaid and The Uninsured, Medicaid Facts: Medicaid and Prescription Drugs (October 2000). BBA admits that such publication exists and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 157 of the Second Amended Complaint.
- 158. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 158 of the Second Amended Complaint.

#### 2. Medicaid prescription drug coverage and payment policies

- 159. BBA admits that 42 C.F.R. § 440.120(a) contains a definition for the term "prescribed drugs." The regulation speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of this regulation. BBA is otherwise without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 159 of the Second Amended Complaint.
- 160.-161. Paragraphs 160-161 of the Second Amended Complaint contain allegations based on information allegedly contained in R. Schwalberg, H. Bellamy, M. Giffin. C. Miller & S.S. Williams, Outpatient Prescription Drug Benefits Under Medicaid: Detailed Case Studies (October 2001). BBA admits that such publication exists

and that this publication speaks for itself. BBA denies the plaintiff's interpretation and characterization of the contents of that publication. In all other respects, BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 160-161 of the Second Amended Complaint.

- 162. BBA admits that Montana Administrative Rule 37.86.1105 (2003) prescribes the reimbursement offered by Montana for "outpatient drugs" under Montana Medicaid Primary Care Services. This Rule speaks for itself. BBA admits that Montana Administrative Rule 37.86.1101(3) (2003) defines "maximum allowable cost" for the purposes of Montana Medicaid Primary Care Services. This Rule speaks for itself. BBA admits that Montana Administrative Rule 37.86.1101(1) (2003) defines "estimated acquisition cost" for the purposes of Montana Medicaid Primary Care Services. This Rule speaks for itself. BBA otherwise is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 162 of the Second Amended Complaint.
- 163. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 163 of the Second Amended Complaint.

# VI. AWP PLAYS A CENTRAL ROLE IN ALL PRESCRIPTION DRUG REIMBURSEMENT SYSTEMS, AND THE TRUTHFUL REPORTING OF AWPS IS ESSENTIAL TO THE INTEGRITY OF THE MARKETPLACE

164. BBA realleges and incorporates herein by reference each of the responses contained in the preceding paragraphs of this Answer. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 164 of the Second Amended Complaint.

- 165. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 165 of the Second Amended Complaint.
- 166. BBA admits that some providers may submit claims for reimbursement in certain circumstances, seeking payment for prescription drugs from Medicare, Medicaid, insurers, and patients, among others. All remaining allegations contained in Paragraph 166 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 166 of the Second Amended Complaint as they relate to defendants other than BBA.
- 167. The allegations contained in Paragraph 167 of the Second Amended Complaint are admitted.
- 168. The allegations contained in the first and fourth sentences of Paragraph 168 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the first and fourth sentences of Paragraph 168 of the Second Amended Complaint as they relate to defendants other than BBA. BBA admits that the Foreward to the 1999 edition of the *Red Book* states, in part, that "[a]ll pricing information in both *Red Book* and the *Updates* is supplied and verified by the products' manufacturers. We believe it to be as timely and accurate as possible. Nevertheless, please note that *Red Book* conducts no independent review, and therefore cannot guarantee the accuracy of these prices." All remaining allegations contained in the second sentence of Paragraph 168 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the second sentence of Paragraph 168 of the

Second Amended Complaint as they relate to defendants other than BBA. BBA admits that a June 1996 article in BARRON'S magazine includes the following statement: "Phil Southerd, associate product manager of the Red Book, says it publishes prices that are faxed right from the manufacturers." BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the excerpted statement. All remaining allegations contained in the third sentence of Paragraph 168 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in the third sentence of Paragraph 168 of the Second Amended Complaint as they relate to defendants other than BBA. BBA is not a party to the litigation identified in the fifth sentence of Paragraph 168 of the Second Amended Complaint. Nonetheless, the specific allegations contained in the fifth sentence of Paragraph 168, including the alleged excerpt, are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the fifth sentence of Paragraph 168, including the alleged excerpt, as they relate to defendants other than BBA.

- 169. The allegations contained in Paragraph 169 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 169 of the Second Amended Complaint as they relate to defendants other than BBA.
- 170. BBA admits that the Office of the Inspector General issued a "Compliance Program Guidance for Pharmaceutical Manufacturers" in April 2003 and that this Guidance includes the portions excerpted in Paragraph 170 of the Second Amended Complaint. The remaining allegations contained in Paragraph 170 of the Second Amended Complaint are denied.

- Program Guidance for Pharmaceutical Manufacturers" in April 2003 and that this Guidance includes the portion excerpted in Paragraph 171 of the Second Amended Complaint, with emphasis added by the plaintiff. BBA denies that any claims have been brought against it under the anti-kickback statute. BBA further denies that the excerpt included in Paragraph 171 of the Second Amended Complaint is an allegation of fact referencing or relating to BBA. Nonetheless, the allegations contained in Paragraph 171 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 171 of the Second Amended Complaint as they relate to defendants other than BBA.
- 172. The allegations contained in Paragraph 172 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 172 of the Second Amended Complaint as they relate to defendants other than BBA.

#### VII. THE AWP INFLATION SCHEME

173.-174. The allegations contained in Paragraphs 173-174 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 173-174 of the Second Amended Complaint as they relate to defendants other than BBA.

#### A. General Outline Of The Scheme For Brand Name Drugs

175. The allegations contained in Paragraph 175 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief

as to the truth or falsity of the specific allegations contained in Paragraph 175 of the Second Amended Complaint as they relate to defendants other than BBA.

#### 1. Artificially Inflating AWPs

176.-180. The allegations contained in Paragraphs 177-180 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 176-180 of the Second Amended Complaint as they relate to defendants other than BBA.

#### 2. Improper Use of Free Samples

181.-183. The allegations contained in Paragraphs 181-183 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 181-183 of the Second Amended Complaint as they relate to defendants other than BBA.

#### 3. Other Hidden and Improper Inducements and Price Reductions

184. The allegations contained in Paragraph 184 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 184 of the Second Amended Complaint as they relate to defendants other than BBA.

#### B. General Outline Of The AWP Inflation Scheme For Generic Drugs

185. The allegations contained in Paragraph 185 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 185 of the Second Amended Complaint as they relate to defendants other than BBA.

- 186. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 186 of the Second Amended Complaint.
- 187. BBA admits that 42 C.F.R. § 405.517 speaks for itself and states, in relevant part, that "[p]ayment for a drug or biological described in paragraph (a) of this section is based on the lower or the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological." BBA admits that 42 C.F.R. § 405.517(c) further states that "[f]or multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological." All remaining allegations contained in Paragraph 187 of the Second Amended Complaint are denied.
- 188. BBA admits that 42 C.F.R. § 447.332(b) and Montana Administrative Rules 37.86.1101(1) and 37.86.1101(3) speak for themselves. BBA denies the plaintiff's interpretation and characterization of the contents of those regulations in Paragraph 188 of the Second Amended Complaint. Therefore, the allegations contained in Paragraph 188 of the Second Amended Complaint are denied as to BBA.
- 189. The allegations contained in Paragraph 189 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to truth or falsity of the specific allegations contained in Paragraph 189 of the Second Amended Complaint as they relate to defendants other than BBA.
- 190. The allegations contained in Paragraph 190 of the Second Amended Complaint are denied as to BBA.

- 191. The allegation contained in Paragraph 191 of the Second Amended Complaint that any one generic manufacturer can affect the median AWP for a given product is denied. The remaining allegations contained in Paragraph 191 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 191 as they relate to defendants other than BBA.
- 192. The plaintiff has failed to identify the source of the alleged quote from an "industry consultant" contained in Paragraph 192 of the Second Amended Complaint. As a result, BBA cannot form a belief as to the accuracy of the alleged quotation. Nonetheless, the allegations contained in Paragraph 192 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 192 as they relate to defendants other than BBA.
- 193. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the allegations contained in Paragraph 193 of the Second Amended Complaint.
- 194. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 194 of the Second Amended Complaint.
- 195. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the first sentence of Paragraph 195 of the Second Amended Complaint. The remaining allegations contained in Paragraph 195 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or

information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 195 of the Second Amended Complaint as they relate to defendants other than BBA.

196. The sources for the chart attached to Paragraph 196 are not sufficiently indicated to allow BBA to form a belief as to the truth or falsity of the information contained therein as it relates to BBA. Nonetheless, the allegations contained in both Paragraph 196 of the Second Amended Complaint and the attached chart are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 196 of the Second Amended Complaint or the attached chart as they relate to defendants other than BBA.

197.-200. BBA is not a party to the litigation identified in Paragraphs 197-200 of the Second Amended Complaint and lacks sufficient information to verify the accuracy of the plaintiff's "summary" of the allegations allegedly contained in the complaint in that litigation. Nonetheless, the allegations contained in Paragraphs 197-200 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 197-200 of the Second Amended Complaint as they relate to defendants other than BBA.

## C. How The AWP Inflation Scheme Impacts Many Private Reimbursement Systems Through PBMs

201.-202. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 201-202 of the Second Amended Complaint.

203.-208. The allegations contained in Paragraphs 203-208 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to

form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 203-208 of the Second Amended Complaint as they relate to defendants other than BBA.

209. The allegations contained in the first sentence of Paragraph 209 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the first sentence of Paragraph 209 of the Second Amended Complaint as they relate to defendants other than BBA. BBA admits that the WALL STREET JOURNAL published an article on March 31, 2003 that discussed, in part, the alleged AWP of fluoxetine, a generic form of Prozac, as well as the prices at which Express Scripts, Inc. allegedly buys and sells the product. BBA denies the plaintiff's interpretation and characterization of the content of that article. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in the article cited in Paragraph 209 of the Second Amended Complaint. BBA denies that the article references or relates to BBA in any way. The remaining allegations contained in Paragraph 209 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 209 of the Second Amended Complaint as they relate to defendants other than BBA.

#### D. Congressional And Other Federal Investigations and Actions

210. BBA admits that the United States Department of Justice, the United States General Accounting Office, and the Office of the Inspector General at the United States Department of HHS have conducted inquiries relating to the government's payment to providers for the administration of certain pharmaceuticals. BBA is without sufficient knowledge or

information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 210 of the Second Amended Complaint.

- 211.-212. BBA admits that Congressman Fortney Pete Stark of California, who was a member of the Subcommittee on Health under the Committee on Ways and Means in the United States House of Representatives, wrote a letter, dated September 28, 2000, to Alan F. Holmer, who was serving as the President of the Pharmaceutical Research and Manufacturers of America. BBA admits that this letter includes the sentence excerpted in Paragraphs 211-212 of the Second Amended Complaint. BBA denies that this letter references or relates to BBA in any way. The remaining allegations contained in Paragraphs 211-212 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraphs 211-212 of the Second Amended Complaint as they relate to defendants other than BBA.
- 213. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 213 of the Second Amended Complaint.

#### E. Examples Of Specific AWP Inflation By Each Defendant

- 214. The allegations contained in Paragraph 214 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 214 of the Second Amended Complaint as they relate to defendants other than BBA.
- 215. The allegations contained in Paragraph 215 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief

as to the truth or falsity of the specific allegations contained in Paragraph 215 of the Second Amended Complaint as they relate to defendants other than BBA.

#### 1. Abbott

216.-233. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 216-233 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 2. Amgen

234.-248. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 234-248 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 3. AstraZeneca

249.-273. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 249-274 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 4. The Aventis Group (Aventis, Pharma, Hoechst and Behring)

274.-295. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 274-295 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 5. Baxter

296.-312. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 296-312 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 6. Bayer

313.-331. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 313-331 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 7. The Boehringer Group

332.-346. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 332-346 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 8. B. Braun

- 347.-348. BBA admits that B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation, manufactures dextrose, dextrose in lactated ringers, dextrose with sodium chloride, heparin sodium (porcine) in d5w, sodium chloride, and sodium chloride (gu irrigant). BBA admits that the plaintiff has identified dextrose, dextrose in lactated ringers, dextrose with sodium chloride, heparin sodium (porcine) in d5w, sodium chloride, and sodium chloride (gu irrigant) as the products allegedly manufactured by BBA that are the subject of the plaintiff's claims against BBA. BBA denies the remaining allegations contained in Paragraphs 347-348 of the Second Amended Complaint.
- 349. The allegations contained in Paragraph 349 of the Second Amended Complaint are denied. The document cited in Paragraph 349 of the Second Amended Complaint was produced, not by BBA, but by B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation. The document cited in Paragraph 349 of the Second Amended Complaint and produced by B. Braun Medical Inc., identified by Bates number BBMDL 000013, speaks for itself. BBA denies the accuracy both of the alleged excerpt from this document and of the

plaintiff's interpretation and characterization of this document in Paragraph 349 of the Second Amended Complaint.

- 350. The allegations contained in Paragraph 350 of the Second Amended Complaint are denied. The document cited in Paragraph 350 of the Second Amended Complaint was produced, not by BBA, but by B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation. The document cited in Paragraph 350 of the Second Amended Complaint and produced by B. Braun Medical Inc., identified by Bates number BBMDL 013372, speaks for itself. BBA denies the accuracy both of the alleged excerpt from this document and of the plaintiff's interpretation and characterization of this document in Paragraph 350 of the Second Amended Complaint.
- 351. The allegations contained in Paragraph 351 of the Second Amended Complaint are denied.

### a. B. Braun's understanding of AWP and intentional manipulation thereof

- 352. The allegations contained in Paragraph 352 of the Second Amended Complaint are denied. Further, the document cited in Paragraph 352 was produced, not by BBA, but by B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation. The document cited in Paragraph 352 of the Second Amended Complaint and produced by B. Braun Medical Inc., identified by Bates number BBMDL 001907, speaks for itself. BBA denies the accuracy both of the alleged excerpt from this document in Paragraph 352 of the Second Amended Complaint and of the plaintiff's interpretation and characterization of the document.
- 353. The allegations contained in Paragraph 353 of the Second Amended Complaint are denied. The document cited in Paragraph 353 of the Second Amended Complaint was produced, not by BBA, but by B. Braun Medical Inc., which has been dismissed as a defendant

in this MDL litigation. The document cited in Paragraph 353 of the Second Amended Complaint and produced by B. Braun Medical Inc., identified by Bates number BBMDL 008056, speaks for itself. BBA denies the accuracy both of the alleged excerpt from this document and of the plaintiff's interpretation and characterization of this excerpt and document in Paragraph 353 of the Second Amended Complaint.

- 354. The allegations contained in Paragraph 354 of the Second Amended Complaint are denied. The document cited in Paragraph 354 of the Second Amended Complaint was produced, not by BBA, but by B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation. The document cited in Paragraph 354 of the Second Amended Complaint and produced by B. Braun Medical Inc., identified by Bates number BBMDL 000011, speaks for itself. BBA denies the accuracy both of the alleged excerpt from this document and of the plaintiff's interpretation and characterization of this excerpt and document in Paragraph 354 of the Second Amended Complaint.
- 355. The allegations contained in Paragraph 355 of the Second Amended Complaint are denied.
- 356. The allegations contained in Paragraph 356 of the Second Amended Complaint are denied. The document cited in Paragraph 356 of the Second Amended Complaint was produced, not by BBA, but by B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation. The document cited in Paragraph 356 of the Second Amended Complaint and produced by B. Braun Medical Inc., identified by Bates number BBMDL 009658, speaks for itself. BBA denies the accuracy of the plaintiff's interpretation and characterization of this document in Paragraph 356 of the Second Amended Complaint.

- 357. The allegations contained in Paragraph 357 of the Second Amended Complaint are denied. The documents cited in Paragraph 357 of the Second Amended Complaint were produced, not by BBA, but by B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation. The documents cited in Paragraph 357 of the Second Amended Complaint and produced by B. Braun Medical Inc., identified by Bates numbers BBMDL 009763, BBMDL 001891, and BBMDL 009658, speak for themselves. BBA denies the accuracy of the plaintiff's interpretation and characterization of these documents in Paragraph 357 of the Second Amended Complaint.
- Amended Complaint that B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation, produced documents in response to subpoenas from the United States Department of Justice, the State of Texas, and the State of California is admitted. The allegation that BBA has produced any documents in response to government subpoenas is denied. The remaining allegations contained in Paragraph 358 of the Second Amended Complaint and the referenced Table 1 are denied.
- 359. The allegations contained in Paragraph 359 of the Second Amended Complaint are denied. The document cited in Paragraph 359 of the Second Amended Complaint was produced, not by BBA, but by B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation. The document cited in Paragraph 359 of the Second Amended Complaint and produced by B. Braun Medical Inc., identified by Bates number BBMDL 011831, speaks for itself. None of the cited products are identified as the subject of the plaintiff's claims against BBA; thus, BBA denies the relevance of this document to this litigation. BBA further denies the

accuracy of the plaintiff's interpretation and characterization of this excerpt and document in Paragraph 359 of the Second Amended Complaint.

#### b. B. Braun provided other improper incentives

- 360. BBA admits that B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation, from time to time may have provided samples of certain of its drug products and may have provided certain educational grants in compliance with applicable law. The remaining allegations contained in Paragraph 360 of the Second Amended Complaint are denied.
- 361. The allegations contained in Paragraph 361 of the Second Amended Complaint are denied. The document cited in Paragraph 361 of the Second Amended Complaint was produced, not by BBA, but by B. Braun Medical Inc., which has been dismissed as a defendant in this MDL litigation. The document cited in Paragraph 361 of the Second Amended Complaint and produced by B. Braun Medical Inc., identified by Bates number BBMDL 002088, speaks for itself. BBA denies the accuracy of the plaintiff's interpretation and characterization of this excerpt and document in Paragraph 361 of the Second Amended Complaint.

#### c. B. Braun has been the target of multiple government investigations

- 362. BBA admits that certain governmental agencies have made an inquiry relating to the government's payment for certain drugs, including certain drugs manufactured by B. Braun Medical Inc. or McGaw, Inc. Nonetheless, the allegations contained in Paragraph 362 of the Second Amended Complaint are denied as to BBA.
- 363. BBA admits that the Department of Health and Human Services issued Program Memorandum AB-00-86 on September 8, 2000 that related to pharmaceutical pricing. BBA further admits that Program Memorandum AB-00-86 was superseded by Program Memorandum

AB-00-115, issued by the Department of Health and Human Services on November 17, 2000. The allegation contained in Paragraph 363 of the Second Amended Complaint that the attachment to Program Memorandum AB-00-86 included references to dextrose, dextrose sodium chloride, and sodium chloride manufactured by McGaw, Inc., which has not been named as a defendant in this action, is admitted. The remaining allegations contained in Paragraph 363 of the Second Amended Complaint and the attached chart are denied.

#### 9. The BMS Group (Bristol-Myers, OTN and Apothecon)

364.-385. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 364-385 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 10. Dey

386.-409. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 386-409 of the Second Amended Complaint. These allegations are directed at another defendant.

## 11. The Fujisawa Group (Fujisawa Pharmaceutical, Fujisawa Healthcare, Fujisawa USA)

410.-422. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 410-422 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 12. The GSK Group (GlaxoSmithKline, SmithKline Beecham, Glaxo Wellcome)

423.-464. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 423-464 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 13. Immunex

465.-480. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 465-480 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 14. The Johnson & Johnson Group (J&J, Centocor and Ortho)

481.-495. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 481-495 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 15. Novartis

496.-503. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 496-503 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 16. Pfizer

504.-511. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 504-511 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 17. The Pharmacia Group (Pharmacia and P&U)

512.-531. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 512-531 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 18. The Schering-Plough Group (Schering-Plough and Warrick)

532.-549. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 532-549 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 19. The Sicor Group (Sicor, Gensia and Gensia Sicor)

550.-567. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 550-567 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 20. TAP

568.-588. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 568-588 of the Second Amended Complaint. These allegations are directed at another defendant.

#### 21. Watson

589.-602. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 589-602 of the Second Amended Complaint. These allegations are directed at another defendant.

#### VIII. DEFENDANTS' "BEST PRICE" FRAUDS

603.-634. The plaintiff's claims relating to "Best Price" have been dismissed by the Court's Memorandum and Order dated June 10, 2004. Thus, no response is required to Paragraphs 603-634 of the Second Amended Complaint.

## IX. DEFENDANTS' CONCEALMENT OF THE TRUTH AND TOLLING OF STATUTES OF LIMITATION

- 635. The allegations contained in Paragraph 635 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 635 of the Second Amended Complaint as they relate to defendants other than BBA.
- 636. BBA admits that the CMS Health Care Industry Market Update dated January 10, 2003, states, in part, "[w]hile PBMs have undoubtedly played an important role in containing

drug costs, actual cost-savings data is difficult to collect because price discounts are closely guarded as competitive information." BBA denies the allegation that this excerpt relates to the conduct of drug manufacturers rather than PBMs. The remaining allegations contained in Paragraph 636 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraph 636 of the Second Amended Complaint as they relate to defendants other than BBA.

637.-643. The allegations contained in Paragraphs 637-643 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 637-643 of the Second Amended Complaint as they relate to defendants other than BBA.

### X. DIRECT DAMAGE SUSTAINED BY THE STATE OF MONTANA, PATIENTS AND THIRD-PARTY PAYORS

644-645. The allegations contained in Paragraphs 644-645 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 644-645 of the Second Amended Complaint as they relate to defendants other than BBA.

646-648. The allegations contained in Paragraphs 646-648 of the Second Amended Complaint have no relation to BBA and are, therefore, denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 646-648 of the Second Amended Complaint as they relate to defendants other than BBA.

- 649. BBA admits that some Medicare beneficiaries may purchase supplemental insurance known as "Medigap" or "Medicare Plus" to cover charges not paid by Medicare. All remaining allegations contained in Paragraph 649 of the Second Amended Complaint are denied.
- 650. The allegations contained in Paragraph 650 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 650 of the Second Amended Complaint as they relate to defendants other than BBA.
- 651. The plaintiff's claims relating to "Best Price" have been dismissed by the Court's Memorandum and Order dated June 10, 2004. Therefore, no response to the allegations contained in Paragraph 651 of the Second Amended Complaint is required.
- 652-653. The allegations contained in Paragraphs 652-653 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 652-653 of the Second Amended Complaint as they relate to defendants other than BBA.

#### XI. CLAIMS FOR RELIEF

# COUNT I DECEPTIVE TRADE PRACTICES (Violations of Mont. Code Ann. § § 30-14-101-1414) CLAIM FOR DAMAGES CAUSED TO MONTANA RESIDENTS

- 654. BBA realleges and incorporates herein by reference each of the responses contained in the preceding paragraphs of this Answer.
- 655-660. The allegations contained in Paragraphs 655-660 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraphs 655-660 of the Second Amended Complaint as they relate to defendants other than BBA.

#### **COUNT II**

#### **DECEPTIVE TRADE PRACTICES**

(Violations of Mont. Code Ann. § § 30-14-101-1414)

## CLAIM FOR CIVIL PENALTIES, INJUNCTIVE RELIEF, AND RESTITUTION FOR THE STATE OF MONTANA

- 661. BBA realleges and incorporates herein by reference each of the responses contained in the preceding paragraphs of this Answer.
- 662.-667. The plaintiff's claims relating to "Best Price" have been dismissed by the Court's Memorandum and Order dated June 10, 2004. Therefore, no response is required to the allegations contained in Paragraphs 662-667 of the Second Amended Complaint relating to "Best Price." All remaining allegations contained in Paragraphs 662-667 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the remaining allegations contained in Paragraphs 662-667 of the Second Amended Complaint as they relate to defendants other than BBA.

## COUNT III MEDICAID FRAUD (Violations of Mont. Code Ann. § 53-6-160) CLAIM FOR COST RECOVERY

- 668. BBA realleges and incorporates herein by reference each of the responses contained in the preceding paragraphs of this Answer.
- 669.-679. Count III has been dismissed by the Court's Memorandum and Order dated June 10, 2004. Therefore, no response is required to Paragraphs 668-679 of the Second Amended Complaint.

### COUNT IV FALSE CLAIMS

#### (Violations of Mont. Code Ann. § 17-8-231) CLAIM FOR FORFEITURE, CIVIL PENALTIES, DOUBLE DAMAGES AND LEGAL COSTS

- 680. BBA realleges and incorporates herein by reference each of the responses contained in the preceding paragraphs of this Answer.
- 681.-691. Count IV has been dismissed by the Court's Memorandum and Order dated June 10, 2004. Therefore, no response is required to Paragraphs 681-691 of the Second Amended Complaint.

## COUNT V PUNITIVE DAMAGES CLAIM BROUGHT ON BEHALF OF THE STATE OF MONTANA

- 692. BBA realleges and incorporates herein by reference each of the responses contained in the preceding paragraphs of this Answer.
- 693. The allegations contained in Paragraph 693 of the Second Amended Complaint are denied as to BBA. BBA is without sufficient knowledge or information so as to form a belief as to the truth or falsity of the specific allegations contained in Paragraph 693 of the Second Amended Complaint as they relate to defendants other than BBA.

#### DEFENSES OF B. BRAUN OF AMERICA INC.

- (1) The plaintiff has failed to state claims against BBA as to which relief can properly be granted.
- (2) BBA has not been properly served with process.
- (3) The Court lacks personal jurisdiction over BBA.
- (4) Venue is improper as to BBA in this Court.
- (5) The plaintiff lacks standing or the capacity to bring some or all of the claims raised in this suit, including but not limited to, the plaintiff's asserted status in *parens patriae* to recover Medicaid or Medicare expenditures or to seek injunctive relief.

- (6) Claims are barred, in whole or in part, by the applicable statutes of limitations.
- (7) Claims are barred, in whole or in part, by the filed rate doctrine.
- (8) State law claims are preempted, in whole or in part, by federal law, including without limitation, the Federal Employment Retirement Income and Security Act of 1974, the Federal Medicare Act, and the Federal Medicaid Act, including all amendments to the same and all regulations promulgated thereunder.
- (9) Claims are preempted by the dormant Commerce Clause of the United States Constitution.
- (10) Claims are barred, in whole or in part, because they violate BBA's rights under the Due Process and *Ex Post Facto* clauses of the United States Constitution, as well as the Constitution of the State of Montana, insofar as the plaintiff seeks to impose liability retroactively for conduct that was not actionable at the time it occurred.
- (11) BBA is not a proper party to this litigation.
- (12) Any actions taken with regard to average wholesale prices were taken in good-faith reliance on the advice of legal counsel.
- (13) Any and all actions taken by BBA with respect to any of the matters alleged in the Second Amended Complaint were taken in good faith and in accordance with established industry practice.
- (14) Claims are barred by the political question and/or separation of powers doctrines.
- (15) To the extent there is recovery on these facts in a separate case, the plaintiff is barred from seeking recovery pursuant to the doctrines of res judicata and/or collateral estoppel, and/or the prohibition on double recovery.
- (16) Claims are barred by the Noerr-Pennington doctrine to the extent they are premised on alleged statements or conduct by any defendant in judicial, legislative and/or administrative proceedings.
- (17) Claims are barred to the extent that the plaintiff has released, settled, entered into an accord and satisfaction and/or otherwise compromised its claims.
- (18) Claims are barred by the doctrines of laches, estoppel and/or waiver.

- (19) Claims for injunctive relief are barred by the doctrines of *in pari delicto* and/or unclean hands.
- (20) Claims for injunctive relief were mooted by the passage of the 2003 Medicare reform legislation.
- (21) Claims are barred due to failure to join indispensable parties.
- (22) Claims for damages are barred for failure to mitigate damages.
- (23) Claims are barred by the doctrine of consent and/or ratification to the extent that plaintiff has received and paid for medicines manufactured, marketed and sold by any defendant after the filing of the original Complaint.
- (24) Claims are barred and/or should be dismissed to the extent that defenses asserted by any other defendant may apply to BBA.

Dated: July 12, 2004

Respectfully subpritted,

Daniel F. Attridge, P.C.

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Attorneys for B. Braun of America Inc.

#### **CERTIFICATE OF SERVICE**

This is to certify that a true and correct copy of the foregoing Answer of B. Braun of America Inc. to State of Montana's Second Amended Complaint has been served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to Verilaw Technologies for posting and notification to all parties on this 12<sup>th</sup> day of July, 2004.

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